

Complete Summary

GUIDELINE TITLE

The solitary pulmonary nodule.

BIBLIOGRAPHIC SOURCE(S)

Tan BB, Flaherty KR, Kazerooni EA, Iannettoni MD. The solitary pulmonary nodule. Chest 2003 Jan; 123(1 Suppl):89S-96S. [55 references] [PubMed](#)

COMPLETE SUMMARY CONTENT

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT

CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Solitary pulmonary nodule (SPN)

GUIDELINE CATEGORY

Diagnosis

Management

CLINICAL SPECIALTY

Nuclear Medicine

Oncology

Pulmonary Medicine

Radiology

Thoracic Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To provide clinically relevant, evidence-based guidelines for appropriate imaging modalities and diagnostic testing, and indications for obtaining preoperative tissue diagnosis for patients with a solitary pulmonary nodule

TARGET POPULATION

Patients with a solitary pulmonary nodule (SPN)

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnostic interventions

1. Chest x-ray (CXR)
2. Spiral computed tomography with contrast
3. Surgical resection
4. Magnetic resonance imaging (MRI) (considered but not recommended routinely)
5. Bronchoscopy (considered but not recommended routinely)
6. Transthoracic needle aspiration (TTNA) or transbronchial needle biopsy
7. Positron emission tomography (PET) scan with 18-fluorodeoxyglucose (FDG)

Management

Therapeutic surgical procedures

1. Wedge resection followed by lobectomy if pathology is positive for cancer
2. Systemic lymph node dissection for all pulmonary resections

Surveillance

1. Two-year follow-up for patients without a definitive tissue diagnosis and marginal surgical candidates with unchanged chest x-rays and a negative positron emission tomography scan.

MAJOR OUTCOMES CONSIDERED

- Sensitivity and specificity of diagnostic tests
- Diagnostic yield

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

As a first step in identifying the evidence for each topic, the guideline developers sought existing evidence syntheses including guidelines, systematic reviews, and meta-analyses. They searched computerized bibliographic databases including MEDLINE, Cancerlit, CINAHL and HealthStar, the Cochrane Collaboration Database of Abstracts of Reviews of Effectiveness, the National Guideline Clearinghouse, and the National Cancer Institute Physician Data Query database. Computerized searches through July 2001 used the MeSH terms lung neoplasms (exploded) and bronchial neoplasms or text searches for lung cancer combined with review articles, practice guidelines, guidelines, and meta-analyses. They also searched and included studies from the reference lists of review articles, and queried experts in the field. An international search was conducted of Web sites of provider organizations that were likely to have developed guidelines. Abstracts of candidate English language articles were reviewed by two physicians (one with methodological expertise and one with content area expertise) and a subset was selected for review in full text. Full-text articles were reviewed again by two physicians to determine whether they were original publications of a synthesis and were pertinent to at least one of the topics of the guideline. Articles described as practice guidelines, systematic reviews, or meta-analyses were included, as were review articles that included a "Methods" section. Included articles were classified according to topic.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The USPSTF scheme offers general guidelines to assign one of the following grades of evidence: good, fair, or poor. In general, good evidence included prospective, controlled, randomized clinical trials, and poor evidence included case series and clinical experience. Trials with fair quality of evidence, for instance, historically controlled trials or retrospective analyses, were somewhere in between. In addition to the strength of the study design, however, study quality also was considered. The USPSTF approach considers well-recognized criteria in rating the quality of individual studies for a variety of different types of study design (e.g., diagnostic accuracy studies and case-control studies). The thresholds for distinguishing good vs fair and fair vs poor evidence are not explicit but are left to the judgment of panelists, reviewers, and members of the executive committee.

Assessment of the Scope and Quality of Clinical Practice Guidelines

Clinical practice guidelines identified from the systematic search were evaluated by at least four reviewers using the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Informal Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Each writing committee received a comprehensive list of existing systematic reviews and meta-analyses as well as guidelines published by other groups. In addition, for five key topics (prevention, screening, diagnosis, and staging [invasive and noninvasive], new systematic reviews were undertaken [see "Description of Methods Used to Collect the Evidence" and "Description of Methods Used to Analyze the Evidence" fields]]. For all other topics, writing committees were responsible for identifying and interpreting studies that were not otherwise covered in existing syntheses or guidelines.

The guidelines developed by the writing committee were distributed to the entire expert panel, and comments were solicited in advance of a meeting. During the meeting, proposed recommendations were reviewed, discussed, and voted on by the entire panel. Approval required consensus, which was defined as an overwhelming majority approval. Differences of opinion were accommodated by revising the proposed recommendation, the rationale, or the grade until consensus could be reached. The evidence supporting each recommendation was summarized, and recommendations were graded as described. The assessments of level of evidence, net benefit, and grade of recommendation were reviewed by the executive committee.

Values

The panel considered data on functional status, quality and length of life, tolerability of treatment, and relief of symptoms in formulating guideline recommendations. Cost was not explicitly considered in the guideline development process. Data on these outcomes were informally weighted, without the use of explicit decision analysis or other modeling. The values placed on types of outcomes varied with clinical scenarios. For example, in some situations they considered life expectancy, such as the effects of early detection. In other situations they weighed quality of life more heavily, such as in palliative care and in interpreting small increases in life expectancy with chemotherapy for stage IV disease.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The guideline developer's grading scheme is a modification of the United States Preventive Services Task Force (USPSTF) grades to allow recommendations for a service when (1) evidence is poor, (2) the assessment of the net benefit is moderate to high, and (3) there is consensus among the expert panel to recommend it. This change was necessary because, unlike preventive services (i.e., the routine offering of tests or treatments to well people) in which the burden of proof is high, clinical decisions about the treatment of patients with lung cancer often must be based on an interpretation of the available evidence, even if it is of poor quality. This adaptation distinguished between interventions with poor evidence for which there is consensus (grade C) and interventions with poor evidence for which there is not consensus (grade I).

Grades of Recommendations and Estimates of Net Benefit

The grade of the strength of recommendations is based on both the quality of the evidence and the net benefit of the service (i.e., test, procedure, etc).

Grade A The panel strongly recommends that clinicians routinely provide [the service] to eligible patients. An "A" recommendation indicates good evidence that [the service] improves important health outcomes and that benefits substantially outweigh harms.

Grade B The panel recommends that clinicians routinely provide [the service] to eligible patients. A "B" recommendation indicates at least fair evidence that [the service] improves important health outcomes and concludes that benefits outweigh harms.

Grade C The panel recommends that clinicians routinely provide [the service] to eligible patients. A "C" recommendation indicates that there was consensus among the panel to recommend [the service] but that the evidence that [the service] is effective is lacking, of poor quality, or conflicting, or the balance of benefits and harms cannot be reliably determined from available evidence.

Grade D The panel recommends against clinicians routinely providing [the service]. A "D" recommendation indicates at least fair evidence that [the service] is ineffective or that harm outweighs benefit.

Grade I The panel concludes that the evidence is insufficient to recommend for or against [the service]. An "I" recommendation indicates that evidence that [the service] is effective is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined, and that the panel lacked a consensus to recommend it.

Net Benefit

The levels of net benefit are based on clinical assessment. Estimated net benefit may be downgraded based on uncertainty in estimates of benefits and harms.

Substantial Benefit: Benefit greatly outweighs harm

Moderate Benefit: Benefit outweighs harm

Small/weak Benefit: Benefit outweighs harm to a minimally clinically important degree

None/negative Benefit: Harms equal or outweigh benefit, less than clinically important.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

After extensive review within the expert panel and executive committee, the guidelines were reviewed and approved by the American College of Chest Physicians (ACCP) Health and Science Policy Committee and then by the American College of Chest Physicians Board of Regents.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Each recommendation is rated based on the levels of evidence (good, fair, poor), net benefit (substantial, moderate, small/weak, none/negative), and the grades of the recommendations (A, B, C, D, I). Definitions are presented at the end of the "Major Recommendations" field.

1. For patients with a solitary pulmonary nodule (SPN) that is visible on chest x-ray (CXR), all previous CXRs should be reviewed. Level of evidence, poor; benefit, substantial; grade of recommendation, C
2. For all patients with previous CXRs, an SPN that is unchanged for >2 years does not require further diagnostic evaluation. Level of evidence, fair; benefit, substantial; grade of recommendation, B
3. For patients with an SPN visible on CXR in which benign central calcification is present, no further diagnostic evaluation is necessary. Level of evidence, good; benefit, substantial; grade of recommendation, A
4. For patients with an SPN, a spiral computed tomography (CT) of the chest with contrast is indicated to better characterize the nodule, parenchyma, and mediastinum. CT can be useful in identifying nodules more likely to be benign and obviate the need for further diagnostic evaluation. Additionally, chest CT plays an important role in staging (as delineated in the chapter on noninvasive staging elsewhere in these guidelines). Level of evidence, good; benefit, moderate; grade of recommendation, B
5. For patients with an SPN, magnetic resonance imaging (MRI) is not indicated except in these special instances. Level of evidence, good; benefit, none; grade of recommendation, D

6. For patient with an SPN <1 cm in size, positron emission tomography (PET) scanning is not currently recommended. Level of evidence, good; benefit, none/negative; grade of recommendation, D
7. For patients with an SPN who are surgical candidates and have a negative mediastinal evaluation on CT, PET scanning with 18-fluorodeoxyglucose (FDG) as an investigational tool, where available, may be warranted. Level of evidence, fair; benefit, moderate; grade of recommendation, B
8. For patients with an SPN who are marginal surgical candidates, if PET scanning with 18-fluorodeoxyglucose results are negative, a repeat CT scan is required at least once in 3 months. Level of evidence, poor; benefit, substantial; grade of recommendation, C
9. For patients with an SPN who are marginal surgical candidates, if there are unchanged results from prior CXRs and negative PET scan findings, serial follow-up is recommended, consisting of an initial CXR, and CT scanning at 3, 6, 12, and 24 months. Level of evidence, fair; benefit, substantial; grade of recommendation, B
10. For the patients with an SPN who are operable candidates, transthoracic needle aspiration (TTNA) is not indicated. Level of evidence, good; benefit, none; grade of recommendation, D
11. For operable patients with an SPN who decline surgical intervention, TTNA or transbronchial needle biopsy is the preferred procedure for establishing a diagnosis. Level of evidence, fair; benefit, substantial; grade of recommendation, B
12. For patients with an SPN who are not operable candidates, or are at high risk, TTNA may be helpful to establish tissue diagnosis. Level of evidence, good; benefit, moderate; grade of recommendation, B
13. For patients with an SPN, bronchoscopy is usually not indicated. Level of evidence, good; benefit, none; grade of recommendation, D
14. For operable patients with an SPN, if the lesion is amenable to a wedge resection, then wedge resection is the procedure of choice followed by a lobectomy if the pathologic finding is positive for cancer. Level of evidence, fair; benefit, substantial; grade of recommendation, B
15. For operable patients with an SPN, if the lesion is not amenable to a wedge resection, a diagnostic lobectomy is acceptable. Level of evidence, good; benefit, substantial; grade of recommendation, A
16. All pulmonary resections, anatomic or nonanatomic, must include a systematic lymph node dissection. Level of evidence, good; benefit, substantial; grade of recommendation, A
17. For patients with an SPN who are marginal surgical candidates, a wedge resection or segmentectomy is acceptable. Level of evidence, fair; benefit, substantial; grade of recommendation, B
18. For patients with an SPN without a definitive tissue diagnosis, a minimum follow-up of 2 years is recommended. This should include an initial CXR, and CT scanning at 3, 6, 12, and 24 months. Level of evidence, poor; benefit, moderate; grade of recommendation, C

Definitions:

Levels of Evidence

In general, good evidence included prospective, controlled, randomized clinical trials, and poor evidence included case series and clinical experience. Trials with

fair quality of evidence, for instance, historically controlled trials or retrospective analyses, were somewhere in between.

Grades of Recommendations and Estimates of Net Benefit

The grade of the strength of recommendations is based on both the quality of the evidence and the net benefit of the service (i.e., test, procedure, etc).

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Grade C The panel recommends that clinicians routinely provide [the service] to eligible patients. A "C" recommendation indicates that there was consensus among the panel to recommend [the service] but that the evidence that [the service] is effective is lacking, of poor quality, or conflicting, or the balance of benefits and harms cannot be reliably determined from available evidence.

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None/negative Benefit: Harms equal or outweigh benefit, less than clinically important.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Diagnostic procedures that provide a timely and accurate diagnosis of a solitary pulmonary nodule (SPN) provide the patient with malignancy the potential for a cancer cure.

POTENTIAL HARMS

Diagnosis

Risks for false-positive and false-negative test results

Complications of transthoracic needle aspiration

The most frequent complication of transthoracic needle aspiration is pneumothorax in 25 to 30% of patients, with 5 to 10% of these patients requiring a chest tube. Pneumothorax is decreased by avoiding crossing pulmonary fissures and multiple punctures of the lung parenchyma. There can be up to a 10% incidence of hemoptysis and hemorrhage, which is increased by the use of cutting needles. Air embolus and tumor seeding are rare, 0.1% and 0.05% respectively.

CONTRAINDICATIONS

CONTRAINDICATIONS

Transthoracic needle aspiration is contraindicated in the patient with a single lung. Relative contraindications to this procedure are the patient with pulmonary hypertension, coagulopathy or a bleeding diathesis, severe chronic obstructive pulmonary disease (COPD), or vascular malformations.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

1. The American College of Chest Physicians (ACCP) is developing a set of PowerPoint slide presentations for physicians to download and use for physician and allied health practitioners education programs.
2. The ACCP is developing a Quick Reference Guide (QRG) in print and PDA formats for easy reference.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Tan BB, Flaherty KR, Kazerooni EA, Iannettoni MD. The solitary pulmonary nodule. Chest 2003 Jan; 123(1 Suppl):89S-96S. [55 references] [PubMed](#)

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Jan

GUIDELINE DEVELOPER(S)

American College of Chest Physicians - Medical Specialty Society

GUIDELINE DEVELOPER COMMENT

The guideline development panel was composed of members and nonmembers of the American College of Chest Physicians (ACCP) who were known to have expertise in various areas of lung cancer management and care, representing multiple specialties from the following 13 national and international medical associations:

- Alliance for Lung Cancer Advocacy, Support, and Education (a patient support group)
- American Association for Bronchology
- American Cancer Society
- American College of Physicians
- American College of Surgeons Oncology Group
- American Society of Clinical Oncology
- American Society for Therapeutic Radiology and Oncology
- American Thoracic Society
- Association of Community Cancer Centers
- Canadian Thoracic Society
- National Comprehensive Cancer Network

- Oncology Nursing Society
- Society of Thoracic Surgeons

The specialties included pulmonary/respiratory medicine, critical care, medical oncology, thoracic surgery, radiation oncology, epidemiology, law, and medical ethics.

SOURCE(S) OF FUNDING

Funding for both the evidence reviews and guideline development was provided through an unrestricted educational grant from Bristol-Myers Squibb, which had no other role in the evidence review or guideline development process or content.

GUIDELINE COMMITTEE

American College of Chest Physicians (ACCP) Expert Panel on Lung Cancer Guidelines

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Primary Authors: Bethany B. Tan, MD; Kevin R. Flaherty, MD; Ella A. Kazerooni, MD; Mark D. Iannettoni, MD, FCCP

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Information about potential conflicts of interest were collected from each member of the expert panel or writing committee at the time of their nomination in accordance with the policy of the American College of Chest Physicians. Information on conflicts of interest for each panelist is listed in the guideline.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available to subscribers of [Chest - The Cardiopulmonary and Critical Care Journal](#).

Print copies: Available from the American College of Chest Physicians, Products and Registration Division, 3300 Dundee Road, Northbrook IL 60062-2348.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

Background Articles:

- Alberts WM. Lung cancer guidelines. Introduction. Chest 2003 Jan; 123(1 Suppl): 1S-2S.

- McCrory DC, Colice GL, Lewis SZ, Alberts WM, Parker S. Overview of methodology for lung cancer evidence review and guideline development. Chest 2003 Jan; 123(1 Suppl): 3S-6S.
- Harpole LH, Kelley MJ, Schreiber G, Toloza EM, Kolimaga J, McCrory DC. Assessment of the scope and quality of clinical practice guidelines in lung cancer. Chest 2003 Jan; 123(1 Suppl): 7S-20S.
- Alberg AJ, Samet JM. Epidemiology of lung cancer. Chest 2003 Jan; 123(1 Suppl): 21S-49S.

Electronic copies: Available to subscribers of [Chest - The Cardiopulmonary and Critical Care Journal](#).

Print copies: Available from the American College of Chest Physicians, Products and Registration Division, 3300 Dundee Road, Northbrook IL 60062-2348.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on June 30, 2003. The information was verified by the guideline developer on July 25, 2003.

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